

LOTRONEX REMS Program Patient Education Sheet

FDA Required Lotronex/losetron hydrochloride Safety Information

What is LOTRONEX/losetron hydrochloride?

- LOTRONEX/losetron hydrochloride is a prescription medicine only for women with severe irritable bowel syndrome (IBS) whose main problem is diarrhea and who did not get the relief needed from other treatments.
LOTRONEX/losetron hydrochloride has not been shown to help men with irritable bowel syndrome (IBS) or patients under age 18.

What is the most serious risk information about LOTRONEX/losetron hydrochloride treatment?

- About 1 out of every 1,000 women who take LOTRONEX/losetron hydrochloride may get serious complications of constipation. About 3 out of every 1,000 women who take LOTRONEX/losetron hydrochloride over a 6-month period may get a serious problem where blood flow to parts of the large bowel is reduced (ischemic colitis).
- The serious condition of ischemic colitis, and other serious complications of constipation, can happen suddenly. These complications may lead to a hospital stay, and in rare cases, blood transfusions, surgery, and death.
- Certain patients may be more likely to develop a serious bowel condition while taking LOTRONEX/losetron hydrochloride. These include older patients, those who have other health problems and those who take other medicines that may cause constipation.

What should I tell my doctor before I start taking LOTRONEX/losetron hydrochloride?

- Tell your doctor about any illnesses you have, or other medicines you are taking or planning to take.

How do I take LOTRONEX/losetron hydrochloride?

- Take LOTRONEX/losetron hydrochloride exactly as your doctor prescribes it.

When should I stop taking LOTRONEX/losetron hydrochloride and call my doctor?

- Stop taking LOTRONEX/losetron hydrochloride and call your doctor right away if you get constipated, if you have new or worse pain in your stomach area (abdomen), or if you see blood in your bowel movements.
- Call your doctor again if the constipation you called about before has not gotten better.
- Do not start taking LOTRONEX/losetron hydrochloride again unless your doctor tells you to do so, if you stopped taking it because you got constipated.
- Talk with your doctor 4 weeks after starting LOTRONEX/losetron hydrochloride to recheck your IBS symptoms.
- Stop taking LOTRONEX/losetron hydrochloride and call your doctor if your IBS symptoms have not improved after 4 weeks of taking 1 mg of LOTRONEX/losetron hydrochloride 2 times a day.
- If you see other doctors about your IBS or possible side effects from LOTRONEX/losetron hydrochloride, tell the doctor who prescribed LOTRONEX/losetron hydrochloride.

This education sheet only discusses the most serious risk information of LOTRONEX/losetron hydrochloride. For more safety information about LOTRONEX/losetron hydrochloride please see the Medication Guide available at www.LotronexREMS.com

Please visit www.LotronexREMS.com for further information.

LOT15051 08/15